

Title (en)  
BILAYER TABLET FORMULATIONS

Title (de)  
ZWEISCHICHTIGE TABLETTENFORMULIERUNGEN

Title (fr)  
FORMULATIONS DE COMPRIMÉ BICOUCHE

Publication  
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Application  
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Abstract (en)  
[origin: WO2011060256A2] The present invention relates to bilayer tablet formulations comprising metformin extended release (XR) or reduced mass metformin XR formulation as the first layer, an SGLT2 inhibitor formulation as the second layer, and optionally a film coating. The present invention provides methods of preparing the bilayer tablet formulations and methods of treating diseases or disorders associated with SGLT2 activity employing the bilayer tablet formulations.

IPC 8 full level  
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**A61K 9/209** (2013.01 - EP US); **A61K 9/282** (2013.01 - US); **A61K 31/132** (2013.01 - RU); **A61K 31/155** (2013.01 - EP US); **A61K 31/403** (2013.01 - EP US); **A61K 31/70** (2013.01 - EP US); **A61K 31/7004** (2013.01 - EP US); **A61K 31/7028** (2013.01 - RU); **A61K 31/7034** (2013.01 - EP US); **A61K 31/7042** (2013.01 - EP US); **A61K 45/06** (2013.01 - EP US); **A61P 3/00** (2018.01 - EP); **A61P 3/04** (2018.01 - EP); **A61P 3/06** (2018.01 - EP); **A61P 3/10** (2018.01 - EP); **A61P 5/50** (2018.01 - EP); **A61P 9/10** (2018.01 - EP); **A61P 9/12** (2018.01 - EP); **A61P 13/12** (2018.01 - EP); **A61P 17/02** (2018.01 - EP); **A61P 25/00** (2018.01 - EP); **A61P 27/02** (2018.01 - EP); **A61P 27/12** (2018.01 - EP); **A61P 43/00** (2018.01 - EP); **A61K 9/2054** (2013.01 - EP US)

C-Set (source: EP US)  
1. **A61K 31/155 + A61K 2300/00**  
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3. **A61K 31/7042 + A61K 2300/00**

Citation (opposition)  
Opponent : Hoefer & Partner Patentanwälte mbB  
• WO 2008116179 A1 20080925 - BRISTOL MYERS SQUIBB [US], et al  
• US 2005266080 A1 20051201 - DESAI DIVYAKANT S [US], et al  
• WO 2005117841 A1 20051215 - BRISTOL MYERS SQUIBB CO [US], et al  
• WO 2008113000 A1 20080918 - NECTID INC [US], et al  
• WO 2007078726 A2 20070712 - MERCK & CO INC [US], et al  
• WO 2009011451 A1 20090122 - TAKEDA PHARMACEUTICAL [JP], et al  
• WO 2009099734 A1 20090813 - MERCK & CO INC [US], et al  
• WO 2009111200 A1 20090911 - MERCK & CO INC [US], et al  
• WO 2009121945 A2 20091008 - BOEHRINGER INGELHEIM INT [DE], et al  
• WO 2009143021 A1 20091126 - BRISTOL MYERS SQUIBB CO [US], et al  
• US 2006057202 A1 20060316 - ANTARKAR AMIT K [IN], et al  
• US 2008234366 A1 20080925 - BINDRA DILBIR S [US], et al  
• US 5955106 A 19990921 - MOECKEL JOERN [DE], et al  
• WO 2010045656 A2 20100422 - NECTID INC [US], et al  
• WO 2010138535 A1 20101202 - BRISTOL MYERS SQUIBB CO [US], et al  
• WO 2011039337 A1 20110407 - BOEHRINGER INGELHEIM INT [DE], et al  
• ANONYMOUS: "View of NCT01002807 on 2009\_10\_26", CLINICALTRIALS.GOV NCT01002807, 26 October 2009 (2009-10-26), XP055585789  
• M. PFISTER ET AL.: "Dapagliflozin, a novel, selective SGLT2 inhibitor, improved glycemic control over 2 weeks in patients with type 2 diabetes mellitus", CLINICAL PHARMACOLOGY & THERAPEUTICS, vol. 85, no. 5, May 2009 (2009-05-01), pages 513 - 519, XP009146835  
• LIST J F ET AL: "Sodium-Glucose Cotransport Inhibition With Dapagliflozin in Type 2 Diabetes", DIABETES CARE, vol. 32, no. 4, April 2009 (2009-04-01), pages 650 - 657, XP055012106  
• U. MANDAL ET AL.: "Formulation and In Vitro Studies of a Fixed-DoseCombination of a Bilayer Matrix Tablet ContainingMetformin HCl as Sustained Release and Glipizideas Immediate Release", DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY, vol. 34, no. 3, 2008, pages 305 - 313, XP055585729  
• J. CALADO: "Dapagliflozin, an oral sodium glucose cotransporter type 2 inhibitor for the treatment of type 2 diabetes mellitus", IDRUGS: THE INVESTIGATIONAL DRUGS JOURNAL, vol. 12, no. 12, December 2009 (2009-12-01), pages 785 - 798, XP009136677  
• LEVIEN T L ET AL: "New drugs in development for the treatment of diabetes", DIABETES SPECTRUM, vol. 22, no. 2, 2009, pages 92 - 106, XP009123031

Cited by  
CN109432030A; EP4212150A1; EP4008318A1; EP4079296A1

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**WO 2011060256 A2 20110519; WO 2011060256 A3 20120315**; AU 2010319343 A1 20120705; AU 2010319343 B2 20140918; BR 112012011726 A2 20200519; CA 2780939 A1 20110519; CA 2780939 C 20180612; CA 2987757 A1 20110519; CA 2987757 C 20210413; CN 102711739 A 20121003; CN 102711739 B 20151216; CN 105193761 A 20151230; CN 105193761 B 20191206; CY 1122575 T1 20200731; CY 2020008 I1 20201125; CY 2020008 I2 20201125; DK 2498758 T3 20181015; EP 2498758 A2 20120919; EP 2498758 B1 20180725;

EP 3315124 A1 20180502; EP 3315124 B1 20210106; ES 2689107 T3 20181108; ES 2856888 T3 20210928; HR P20181347 T1 20181019; HU E040486 T2 20190328; HU S2000009 I1 20200629; JP 2013510873 A 20130328; JP 2015110630 A 20150618; JP 2017081943 A 20170518; JP 2018172418 A 20181108; JP 5775522 B2 20150909; JP 6367299 B2 20180801; JP 6622862 B2 20191218; LT 2498758 T 20181126; LT C2498758 I2 20210712; LT PA2020003 I1 20200511; MX 2012005416 A 20120614; MX 345777 B 20170214; NO 2020009 I1 20200504; PL 2498758 T3 20190228; PT 2498758 T 20181023; RS 57756 B1 20181231; RU 2012123947 A 20131220; RU 2016112599 A 20181128; RU 2016112599 A3 20190820; RU 2583920 C2 20160510; RU 2712757 C2 20200131; RU 2712757 C3 20210609; SI 2498758 T1 20181030; US 2012282336 A1 20121108; US 2013330406 A1 20131212; US 2015238421 A1 20150827; US 2017333353 A1 20171123; US 8535715 B2 20130917; US 9050258 B2 20150609; US 9616028 B2 20170411

DOCDB simple family (application)

**US 2010056529 W 20101112**; AU 2010319343 A 20101112; BR 112012011726 A 20101112; CA 2780939 A 20101112; CA 2987757 A 20101112; CN 201080061414 A 20101112; CN 201510724956 A 20101112; CY 181100994 T 20180926; CY 2020008 C 20200428; DK 10782113 T 20101112; EP 10782113 A 20101112; EP 17206106 A 20101112; ES 10782113 T 20101112; ES 17206106 T 20101112; HR P20181347 T 20180823; HU E10782113 A 20101112; HU S2000009 C 20200430; JP 2012539017 A 20101112; JP 2015019633 A 20150203; JP 2016237490 A 20161207; JP 2018127638 A 20180704; LT 10782113 T 20101112; LT PA2020003 C 20200424; MX 2012005416 A 20101112; NO 2020009 C 20200504; PL 10782113 T 20101112; PT 10782113 T 20101112; RS P20181067 A 20101112; RU 2012123947 A 20101112; RU 2016112599 A 20101112; SI 201031743 T 20101112; US 201013509210 A 20101112; US 201313965879 A 20130813; US 201514706077 A 20150507; US 201715450918 A 20170306